40 CFR Parts 797 and 799

[OPTS-42071; TSH-FRL 2905-5]

Octamethylcyclotetrasiloxane; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under section 4 of the Toxic Substances Control Act (TSCA), EPA is proposing that manufacturers and processors conduct chemical fate and environmental effects tests for octamethylcyclotetrasiloxane (OMCTS, CAS No. 556-67-2). The proposed testing includes: Biodegradation studies and a number of environmental effects studies including acute toxicity studies in fish, invertebrates, amphipods, oysters, and algae; chronic toxicity studies in fish and invertebrates; bioconcentration potential in fish and oysters; and a mallard reproduction test. This notice constitutes EPA's response to the Interagency Testing Committee's (ITC) designation of OMCTS for priority testing consideration.

DATES: Submit written comments on or before December 30, 1985. If persons request time for oral comment by December 16, 1985, EPA will hold a public meeting on this proposed rule in Washington, DC. For further information on arranging to speak at the meeting see Unit IX of this preamble.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42071), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St., SW., Washington, DC 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460. Toll free: (800-424-9065). In Washington, DC: (554-1404). Outside the USA: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a proposed test rule under section 4(a) of TSCA in response to the ITC's designation of octamethylcyclotetrasiloxane for chemical fate and environmental effects testing consideration.

I. Introduction.

A. ITC Recommendation

TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established the ITC under section 4(e) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated octamethylcyclotetrasiloxane (OMCTS) (CAS No. 556-67-2) for priority consideration for chemical fate and environmental effects tests in its 15th Report, published in the **Federal Register** of November 29, 1984 (49 FR 46931). The ITC recommended that OMCTS be tested for chemical fate including water solubility, octanol/water partition coefficient, and biodegradation studies. It also recommended a tiered series of ecological effects tests including acute toxicity testing of several species using measured concentrations of OMCTS. The ITC further recommended that chronic toxicity studies in aquatic organisms be required conditional upon review of the results of the acute tests.

The ITC's testing recommendations were based upon a steadily increasing U.S. production volume (between 20 and 25 million pounds by one major manufacturer in 1982). While about 80 percent of OMCTS is consumed as a chemical intermediate in the production of various silicone polymers, the remainder is used in a variety of non-consumptive applications from cosmetic or medicinal bases to ingredients in polishes and cleaners. The uses of the polymers themselves are myriad. The multiple uses of OMCTS and its polymers indicate that release and environmental exposure to silicones are extensive. Polyorganosiloxanes have been found in effluents from waste treatment plants, in sediment cores, in river water, and in fish. Computer simulation models (EXAMS and ENPART) predict that OMCTS will partition to the atmosphere and to soils (Refs. 1 and 2). However, very few experimental data have been collected to verify these predictions, or to assess the degree of persistence. Therefore, the chemical properties and environmental fate of OMCTS need to be delineated. The ITC further stated that although a number of tests to determine the acute toxicity to fish and other aquatic organisms have been submitted, none of these tests used measured concentrations of OMCTS; therefore, the interpretation and validity of these tests should be questioned. The ITC recommended that the acute toxicity to fish, aquatic invertebrates, and algae be retested and that concentrations of OMCTS be measured during the course of these studies.

No health effects tests were recommended by the ITC. According to the ITC, commercial products containing OMCTS have been tested extensively in microbiological and tissue culture systems, in standard laboratory mammals (rats, rabbits, etc.), and also in human volunteers with no adverse effects.

B. Test Rule Development Under TSCA

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance to develop appropriate test data if the Administrator finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment.

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities,

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and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture.

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in making a section 4(a)(1)(A)(i) finding; both exposure and toxicity information are considered in determining whether available data support a finding that the chemical may present an unreasonable risk. For the finding under section 4(a)(1)(B)(i), EPA considers only production, exposure and release information to determine whether there is or may be substantial production and significant or substantial human exposure or substantial release to the environment. For the findings under sections 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the finding under section 4(a)(1)(A)(iii) or 4(a)(1)(B)(iii) that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings apply is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48524) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) findings are discussed in 46 FR 48524 and 46 FR 30300, and the section 4(a)(1)(B) findings are discussed in 45 FR 30300.

In evaluating the ITC's testing recommendations concerning OMCTS, EPA considered all available relevant information including the following: information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers of OMCTS under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); health and safety studies submitted under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716) concerning OMCTS; and published and unpublished data available to the Agency. Based on its evaluation, as described in this proposed rule, EPA is proposing chemical fate and environmental effects testing requirements for OMCTS under section 4(a)(1)(A) and under section 49(a)(1)(B). By these actions, EPA is responding to the ITC's designation of OMCTS for priority testing consideration.

II. Review of Available Data

A. Profile, Production and Use

Octamethylcyclotetrasiloxane (OMCTS) is a silicone compound, better known by industry as D_4 because of its tetrameric structure. OMCTS is a colorless oily liquid with little solubility in water (less than 0.5 ppm) (Refs. 3 and 4) and a marked tendency to partition away from water and nonorganic materials into organic materials present in water or soil and sediments (K_{ow} = 4.45: K_{oc} = 3.8) (Refs. 5 through 7). OMCTS is relatively volatile (VP = 1 mm hg at 20°C) (Ref. 8) and will evaporate from water or soil surfaces into the atmosphere where it is destroyed by both hydroxyl free-radicals as well as singlet oxygen atoms from ozone. The atmospheric half-life is dependent upon the dominant reactive species; however, it has been estimated at around 13 days (Refs. 9 through 12).

The production volume of OMCTS has risen dramatically in the last decade. The TSCA Inventory reported 1977 production levels of 1 to 10 million pounds (Ref. 13). By 1982, production had increased to 20 to 25 million pounds (Ref. 14). Aggregate production and importation figures for 1984, from confidential business information submitted under section 8(a) of TSCA, are between 110 to 130 million pounds.

OMCTS is synthesized from a mixture of chloromethyl-silanes, which are themselves synthesized at the same manufacturing facilities (Refs. 15 and 16). To obtain a particular siloxane, e.g. OMCTS, the precursor silane is separated and purified from this mixture by fractional distillation procedures. The purified silane is then hydrolyzed to form the cyclic siloxane or silicone, which is then collected by fractional distillation. Side products and any unreacted silanes are recycled back into the production process. With careful recycling, there is no appreciable loss of either OMCTS or other reactants or products. Gas-liquid chromatography is used to verify the absence of OMCTS in waste material as well as the purity of the final OMCTS produced. This is the standard method of siloxane manufacture employed by all producers; the only difference among the companies is their choice of catalysts employed in the reactions.

About 80 percent of the OMCTS produced or imported is used on-site an intermediate in the production of polydimethylsiloxane (PDMS) polym. of different viscosities (Refs. 8, 14, and 17). The silicone products manufactured include dispersible surface-active agents, propellants, lubricants, caulks, sealants (especially for high temperature or outdoor use), automobile transmission seals, hoses, wire coatings, and various rubber products such as spark plug cables or the flexible portion of gas masks (Refs. 8, 14, 17). Some companies produce a full range of polymers; other have a more restricted line but produce large volumes of these.

OMCTS that is not channeled into polymer production (about 20 percent) is used as part of formulations containing from 3 to 95 percent of OMCTS (Refs. 8, 14, and 18). These include bases or aerosols for spray cleaners and polishes, as well as an anticaking agent in pesticides. It is used in paper and textile sizing, in detergent manufacture, in industrial cleaning solutions, and as a surfactant in waste water treatment plants. For example, General Electric AF60® defoamer (30 percent OMCTS) is used in ink and water based paint manufacture. Dow Corning Antifoam A® (10 percent OMCTS) is employed as a surfactant in sewage treatment plants (Ref. 14). OMCTS is specifically chosen in most of these formulations because is volatile and will evaporate readily

B. Release and Exposure

The diverse and substantial consumer use of OMCTS-containing products, both non-TSCA as well as TSCA regulated (such as cleaners, polishes, and antifoam agents in a variety of chemical and biological processes), indicates that it has been and will continue to be released over wide geographical areas in low but constant levels. The ITC was not concerned at this time with consumer (or general population) exposure or with exposure in the workplace. Commercial products containing OMCTS have been tested extensively in microbiological and tissue culture systems, in standard laboratory mammals (rats, rabbits, monkeys, etc.), and also in human volunteers with no adverse health effects (Ref. 8). However, the ITC was concerned about possible environmental effects resulting from such large scale use.

The amount of OMCTS which is released to the environment as a result of manufacturing is small; release levels have been submitted as confidential

business information. All plant processes are closed, and, as far as possible, OMCTS is retrieved and recycled. Small amounts of volatile siloxanes are lost when process vents are scrubbed. The process water and waste material that are not recycled are treated on-site. Solid waste is incinerated or transported to landfill sites (Refs. 15 and 16).

Because of the volatile nature of OMCTS, it is expected that all of the OMCTS channeled into non-polymer uses (about 25 million pounds) is released to the environment. There are no data that actually quantify OMCTS levels in the general environment. However, industry, just prior to publication of this proposed rule, submitted a study focusing on environmental levels of OMCTS, which will be evaluated with other public comments to the proposed rule.

The available reports detail concentrations of total extractable organic silicones using atomic absorption with a nitrous oxide flame atomizer. Because the detection level of silicon for this method is approximately 0.5 ppm, large samples were concentrated to allow quantification at ppb levels. Pellenbarg (Ref. 19) reported levels of silicones in filter cake, sludge, and aqueous effluent from the Blue Plains wastewater treatment plant in Washington, D.C. Average values were 36.2 parts per million (ppm), 96.1 ppm, and 0.0045 ppm, respectively. Surface sediments of the Potomac River near Washington contained from 0.46 to 3.07 ppm. The higher values were associated with sediments near the treatment plant.

In a 1982 study, Pellenbarg measured silicones in the aqueous surface microlayer of Chesapeake Beach, MD, and the Delaware Bay (Ref. 20). Levels obtained ranged from 24 to 41 parts per billion (ppb) and 23 to 44 ppb, respectively. Organosilicone content of sediment cores from the Delaware Bay ranged from below detection limits to 1.2 ppm. Sediment samples taken from the upper reaches of the Chesapeake Bay to its mouth contained silicone levels from 0.2 to 36.1 ppm. Generally sediments with the higher silicone levels were found in the northern part of the Bay. Where flocculation might occur (promoting settling of particulates containing silicones), values were frequently found in the higher ranges. Higher sedimentary silicone content was found where the shallow upper Bay gives way to the deeper Chesapeake Channel. This region traps sediment moving towards the ocean from such potential urban silicone sources as Baltimore. However, it was not possible to clearly define the effect of urban (and sewage treatment plant effluents) on sedimentary silicone content.

Several sites were sampled by Pellenbarg near a primary dump site in the New York Bight. Organic silicone content of sediments ranged from below the detection limit (not given) to 47.9 ppm (Ref. 21).

Other studies report organosiloxanes in effluents and sludges in Japan (Refs. 22 and 23). Waste from four dyeing factories gave an average value of 0.3 ppm and 2,400 ppm for effluent and sludge, respectively. Sewage treatment plant waste contained 10 ppb (effluent) and 144 ppm (sludge); a wastewater plant effluent contained 3.6 ppb organosilicones. Other studies by Watanabe quantified organosilicones in river waters (13 ppb, 54 ppb), river sediments (1.3 ppm, 5.8 ppm), and sewage sludge (8.5 ppm). Some of the levels for aqueous siloxanes in these Japanese studies are high compared to Chesapeake Bay values. Therefore, these studies do not really confirm the levels reported by Pellenbarg.

Besides evidence of exposure in the Cheaspeake Bay area and in Japan, a paper by de Groot reports ppb levels of OMCTS in Rhine River water (Ref. 24).

A potentially significant point source of environmental exposure results from the use of silicone-containing antifoaming agents in waste treatment plants. For example, Dow Corning Antifoam A® contains 10 percent OMCTS (Ref. 14). During the period October 1977 to October 1978, about 113,000 pounds of antifoam (Dearex 1150®) was purchased by the Blue Plains treatment plant (Ref. 25). If Dearex 1150®(formulation not obtainable (Ref. 26)) contained the same level of OMCTS as Antifoam A®, this implies that 11,300 pounds of OMCTS would be potentially released to the environment from this one plant, either through volatilization in the aeration procedure or by binding to the treated sludge. It is notable that, in several of the studies, organosilicone samples have been associated with, or collected near, waste treatment facilities.

C. Chemical Fate

The persistence of OMCTS (or its polymers) trapped in soils, sediments, and sludges is not well defined. There is general disagreement over the potential for OMCTS to biodegrade. There are several studies on record to measure the biological oxygen demand (BOD) of OMCTS and other polydimethsiloxanes in soils. (Refs. 27 through 29). However the results of these studies are questionable: The negative findings for OMCTS biodegradability may result from OMCTS insolubility in the system tested. Likewise the volatility may affect the results. Industry contends that OMCTS is not biodegradable to any appreciable extent. Since water-soluble methyl siloxanols (which are similar to OMCTS) have no BOD, industry contends that OMCTS solubility or insolubility is not a crucial factor in testing OMCTS for BOD (Refs. 30 and 31). Industry further suggests that OMCTS is too volatile to survive aeration processing in sewage waste treatment plants and would therefore not be present in lagoon sludges. Thus, it would not be found in the sediments of waste-receiving streams or rivers. Industry suggests that the BOD of OMCTS is of academic interest only (Refs. 30 and 31). However other studies of organosiloxanes suggest a potential to biodegrade (Ref. 32). It has been shown that dimethylsilicones can methylate mercury in abiotic systems (Ref. 33). This suggests a potential for OMCTS to act as a methyl donor in a degradative system and perhaps in a biodegradative system. Thus, the data available are questionable, the results are inconclusive, and the persistence of OMCTS in soils, sludges, and sediments cannot be assessed.

Knowledge of the degradation rate of OMCTS in the atmosphere and the persistence or nonpersistence of OMCTS in soils is not by itself enough to assess environmental levels of this silicone. Very little is known about the percentage of OMCTS released directly or indirectly, *e.g.*, through aeration processes in sewage treatment plants, to the atmosphere, and the percentage that is sorbed to sludges or soils or deposited in solid waste disposal sites. Additional data are needed to assess the environmental distribution of this chemical.

D. Environmental Effects

While a number of environmental effects studies have been conducted using either OMCTS itself or one of the formulations containing OMCTS, very few of these studies can be used to assess risk to the environment. In many of these studies, no account was taken of the solubility in water or the volatility of OMCTS, and the resultion data are of little value in characterizing the environmental hazard potential of OMCTS. In other cases the design of the study itself was not appropriate to the testing question being asked.

1. *Acute toxicity.* a. *Fish.* Static studies (96-hr) are available for bluegill sunfish (*Lepomis marochirus*), rainbow trout (*Salmo gairdneri*), and mummichogs (*Fundulus heteroclitus*)

using TX–1283 (a composite of 75 to 80 percent OMCTS and 20 to 25 percent other siloxanes) (Ref. 33). The 96–hour median tolerance limit (TL_{50}) is reported as greater than 1,000 ppm for these species. However, the results are compromised because, while the compound was added at specified concentrations, no measurements were made during the experiment. Moreover, unless TX–1283 (added far in excess of its water solubility) forms an emulsion stable over 96 hours, which is unlikely, the resulting two-phase system will not provide data that can be extrapolated to other systems. A third defect in experimental design is a lack of concern for the volatility of OMCTS. Because of these deficiencies, the studies are not satisfactory.

b. *Aquatic invertebrates.* The static acute toxicity of OMCTS to *Daphnia* was investigated using a range of test concentrations up to 1,000 ppm OMCTS (Ref. 34). The 72–hour median lethal concentration (LC_{50}) was reported as 23.44 ppm. However, the actual concentrations of OMCTS to which *Daphnia* were exposed were not measured. Therefore, while OMCTS induced lethality at the lower end of the nominal concentrations range tested, the actual lethal OMCTS level is not known and could be below the solubility limit of 0.5 ppm. Static tests of TX–1283 (75–80 percent OMCTS) using the same type protocol were also run on shore crabs and grass shrimp. No lethality was seen (Ref. 33).

c. *Other organisms.* OMCTS toxicity to insects and mites was investigated using standard screening procedures. No toxicity was shown at concentrations of 1,000 ppm (Ref. 35). As well, OCMTS is reported to have had no effect on growth of blue-green algae at concentrations up to 2,000 ppm (Ref. 36). As in other studies, there was no control over volatilization and no measured OMCTS levels, therefore these studies should be repeated.

2. *Chronic toxicity.* There was no information on the chronic toxicity of OMCTS to the environment.

3. *Bioconcentration in fathead minnow.* Information was submitted on three bioconcentration tests with fathead minnows (Refs. 37and 38). These tests have been reviewed by the Agency (Ref. 39). Two tests were static tests in which fish were exposed to nominal OMCTS concentrations. Based upon the high log P, the relatively high vapor pressure, and the low water solubility of OMCTS, these static tests were not appropriate, and the reported results confirmed this. A 14-day flow-through test was subsequently done, however the test protocol was seriously flawed and did not follow minimum good laboratory practice guidelines. Because of the shortcomings in experimental design in all three tests, they are considered screening tests. However, the results are sufficient to demonstrate that OMCTS is highly bioconcentrated by fish and that depuration is not rapid.

Based upon the available information, these data are not sufficient to accurately estimate the steady-state bioconcentration factor (BCF) of OMCTS in fish and the time to 50 and 90 percent depuration. These data are sufficient however to demonstrate that OMCTS is rapidly bioconcentrated in fish and that the level of bioconcentration is very high, on the order of 10,000. These data also indicate that OMCTS is not rapidly excreted or metabolized by fish.

III. Findings for Chemical Fate and Environmental Effects

EPA is basing its proposed testing of OMCTS on the authority of sections 4(a)(1)(A) and 4(a)(1)(B) of TSCA. The Agency finds that the use and disposal of OMCTS may present an unreasonable risk of toxicity to the environment. A preliminary bioconcentration study reveals an extremely high BCF in fathead minnows on the order of 10,000. This raises concern that OMCTS may bioaccumulate and may pose acute and/or chronic toxicity hazards in organisms up the trophic chain. There are no other environmental effects data confirming or disputing this finding. The Agency finds that data are insufficient to reasonably determine or predict environmental toxicity effects as a result of use and disposal of OMCTS, and that testing is necessary to develop such data. EPA is therefore proposing that testing be conducted to develop these data under TSCA section 4(a)(1)(A).

EPA finds that OMCTS is produced and imported in substantial quantities and that substantial environmental release of OMCTS occurs. Annual production of OMCTS has risen in the last decade from 1 million to over 100 million pounds per year, and production is expected to continue to increase. EPA finds that the available data are insufficient to reasonably determine or predict the chemical fate and environmental effects of OMCTS release to the environment in the use and disposal of products containing this chemical and that testing is necessary to develop such data.

Although chemical fate testing for water solubility and for the octanol/water partition coefficient were proposed by the ITC, the Agency, after a review of the data, has determined that valid experimental values for these two parameters now exist. Thus, no further testing in this area is necessary.

The Agency finds that there are no satisfactory data available on the biodegradation of OMCTS in soils and sediments. Moreover, there is strong disagreement in the scientific community over whether or not OMCTS would be biodegradable, although little testing itself has been done. Because OMCTS binds strongly to soils and sediments, with demonstrated levels ranging from 1 to 100 ppm, and because the persistence of OMCTS in these soils cannot be determined, a battery of soil biodegradation tests is needed for EPA to adequately assess the chemical fate of OMCTS.

EPA has reviewed and evaluated the existing acute toxicity data for aquatic organisms. In all acute toxicity experiments, levels of OMCTS were based on nominal rather than measured concentrations. With the high volatility and low water solubility of OMCTS, and in light of the duration of some of these experiments (48 to 96 hours), EPA finds these data inadequate to evaluate the acute toxicity of OMCTS.

EPA also finds that in addition to the studies recommended by the ITC, other acute toxicity studies of aquatic vertebrates, invertebrates, and algae are needed to completely assess the acute toxicity of OMCTS. As well, a sediment toxicity test using the invertebrate amphipod *Rhepoxynius* is needed, because PDMS (presumably including OMCTS) is found in ppm levels in aquatic sediments and sludges.

EPA finds that there are no chronic toxicity data for aquatic species available on OMCTS. A bioaccumulation test in fathead minnow has been submitted by industry. This study was reviewed by the Agency; the results, while preliminary, indicate a high potential for bioconcentration (yielding a bioconcentration factor (BCF) on the order of 10,000). To adequately assess the chronic effects of OMCTS to the environment and the possible entry of OMCTS into the food chain via bioaccumulation mechanisms, the Agency finds data are needed to evaluate both the chronic toxicity potential and the bioconcentration potential of OMCTS.

IV. Proposed Rule

A. Proposed Testing and Test Standards

On the basis of the findings given above for chemical fate and environmental effects testing (Unit III), EPA is proposing the following chemical fate and environmental effects tests be

conducted in accordance with specific test guidelines set forth in Title 40 of the Code of Federal Regulations as enumerated below. Test methods under new Parts 796.797 and 798 were published in the **Federal Register** of September 27, 1985 (50 FR 39252). Chemical fate testing of OMCTS shall be conducted to determine: (1) The biodegradability in water, using the eco-core method described by Bourquin et al. (Ref. 40); (2) the aerobic and anaerobic biodegradability in soil, using the guideline entitled "Inherent Biodegradability in Soil" Specified in 40 CFR § 796.3400; and (3) the biodegradability in sludge systems, using the guideline entitled "Inherent Biodegradability: Modified SCAS (Semi-continuous activated sludge) Test for low water soluble compounds" specified in 40 CFR § 796.3341 which appears in the **Federal Register** with the proposed rule for pentabromoethylbenzene and a copy of which is in the docket for OMCTS.

Environmental effects testing of OMCTS shall be conducted to determine: (1) The acute toxicity to the aquatic vertebrates: *Pimephales promelas* (fathead minnow), *Salmo gairdneri* (rainbow trout), *Lepomis macrochirus* (blue gill sunfish), *Cyprinodon variegatus* (sheepshead minnow), and *Menidia peninsulae* (silversides), using flow-through systems with concentrations of OMCTS measured at several intervals during the testing period (due to the volatility of the test substance). The guideline entitled "Fish Acute Toxicity Test", specified in 40 CFR 797.1400, as modified in this proposal, shall be used. (2) The acute toxicity to the invertebrate *Daphnia magna* or *D. pulex*, using flow-through systems with concentrations of OMCTS measured at several intervals during the testing period. The guideline entitled "Daphnid Acute Toxicity Test", specified in 40 CFR § 797.1300, shall be used. (3) The acute toxicity to the invertebrate *Mysidopsis bahia* (mysid shrimp), using flow-through systems with concentrations of OMCTS measured at several intervals during the testing period. The guideline entitled "Mysid Shrimp Acute Toxicity Test", specified in 40 CFR § 797.1930, shall be used. (4) The acute toxicity to the invertebrate *Crassostrea virginica* (oyster), using flow-through systems with concentrations of OMCTS measured at several intervals during the testing period. The guideline entitled "Oyster Acute Toxicity Test", specified in 40 CFR 797.1800, shall be used. (5) The acute toxicity to a freshwater alga, *Selenastrum capricornutum*, and a saltwater alga, *Skeletonema costatum*, using the test guideline entitled "Algal Acute Toxicity Test", specified in 40 CFR 797.1050, and as modified in § 799.1300 (e)(5)(i)(B) shall be used. Concentrations of OMCTS shall be measured at several intervals during the testing period. (6) The marine sediment toxicity to the amphipod (*Rhepoxynius abronius*) using OMCTS-spiked clean sediments having low, medium, and high clay content according to the method of R.C. Swartz et al., "Phoxocephalid Amphipod Bioassay for Marine Sediment Toxicity," as published in the American Society for Testing and Materials Special Technical Publication 854, R.D. Cardwell et al. (eds.), American Society for Testing and Materials, Philadelphia, 1985, pp. 284–307.

EPA is also proposing that: (7) The most sensitive fish (i.e., the fish with the lowest LC_{50} as determined by the above proposed acute toxicity test) be tested for chronic toxicity, using the guideline entitled "Fish Early Life Stage Toxicity Test" specified in 40 CFR 797.1600. Measured concentrations of OMCTS and flow-through systems as specified for the acute toxicity tests shall be employed. (8) The invertebrate *Daphnia* shall be tested to determine the chronic toxicity of OMCTS, using the guideline entitled "Daphnid Chronic Toxicity Test" specified in 40 CFR 797.1330. Measured concentrations of OMCTS and flow-through systems as specified for the acute toxicity tests shall be used. (9) The invertebrate *Mysidopsis bahia* (mysid shrimp) shall be tested to determine the chronic toxicity of OMCTS, using the guideline entitled "Mysid Shrimp Chronic Toxicity Test" specified in 40 CFR 797.1950. Measured concentrations of OMCTS and flow-through systems as specified for the acute toxicity tests shall be used.

EPA further proposes (10) a bioconcentration test in fathead minnow *(Pimephales promelas)* using the guideline entitled "Fish Bioconcentration Toxicity Test" specified in 40 CFR 797.1520, and (11) a bioconcentration test in oyster *(Crassostrea virginica)* using the guideline entitled "Oyster Bioconcentration Test" specified in 40 CFR 797.1830. Measured concentrations of OMCTS and flow-through systems as specified for the acute toxicity tests shall be used. In addition to the potential to bioaccumulate, EPA is concerned that OMCTS may enter the food chain. Since OMCTS may affect avian species in a different manner than aquatic vertebrates or mammals, the Agency is proposing (12) a reproduction test in Mallard ducks, using the guideline entitled "Mallard Reproduction Test" specified in 40 CFR 797.2150.

Further, the following performance criteria shall be met, whether open or closed sytems, static or flow-through methods are used: (1) In all tests CTS levels shall be monitored (measured) immediately prior to the start of the testing period, at a minimum of six intervals during the testing period, and at the end of the test. (2) In the aquatic toxicity tests the level of OMCTS as measured shall be maintained at a level greater than or equal to the initial concentration measured at the beginning of the testing period.

The Agency is proposing that the above referenced chemical fate and environmental effects test guidelines and other cited method be considered the test standards for the purposes of the proposed tests for OMCTS. The test guidelines for chemical fate and aquatic toxicity testing specify generally accepted minimal conditions for determining chemical fate and toxicity to aquatic organisms for substances like OMCTS to which aquatic life is expected to be exposed. The Agency's review of the guidelines, which occurs on a yearly basis according to the process described in 47 FR 41857 (September 22, 1982), has found no reason to conclude that these protocols need to be modified significantly.

EPA intends to propose shortly in a separate **Federal Register** notice certain revisions to these TSCA Test Guidelines to provide more explicit guidance on the necessary minimum elements for each study. In addition, these revisions will avoid repetitive chemcial-by-chemical changes to the guidelines in their adoption as test standards for chemical-specific test rules. EPA is proposing that these modifications be adopted in the test standards for OMCTS.

The proposed eco-core method of Bourquin et al. for testing the biodegradability of OMCTS in water specifies generally accepted minimal conditions. The Agency believes that this test reflects current state-of-the-art methods for testing the fate of OMCTS in aquatic systems.

The ASTM guideline specifies, in EPA's judgement, minimal test conditions and practices for acceptable investigations of the acute sediment toxicity of OMCTS to marine amphipods. Although the Agency has not published a test guideline for sediment toxicity, the ASTM testing procedure reflects the current state-of-the-art for such testing and is being proposed as an acceptable method of

testing OMCTS sediment toxicity to benthic invertebrates.

B. Test Substance

EPA is proposing that OMCTS of 99.0 percent purity be used as the test substance. OMCTS of this purity is commercially available at nominal cost. EPA has specified a highly pure substance for testing because the Agency is interested in evaluating the effects attributable to OMCTS itself.

C. Persons Required To Test

Section 4(b)(3)(B) specifies that the activities for which the Agency makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the findings are based on use, distribution, or disposal.

Because EPA has found that there are insufficient data and experience to reasonably determine or predict the effect of the use and disposal of OMCTS on the environment, EPA is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process, OMCTS at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements contained in this proposed rule. The end of the reimbursement period will be 5 years after the last final report is submitted.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

When both manufacturers and processors are subject to a test rule, EPA expects that manufacturers will conduct the testing and that processors will ordinarily be exempted from testing. As described in 40 CFR Part 790, processors will be granted an exemption automatically without filing application if manufacturers perform all of the required testing. Manufacturers are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the test rule.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for OMCTS. As noted in Unit IV.B above, EPA is interested in evaluating the effects attributable to OMCTS itself and have specified a relatively pure substance for testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking.

D. Reporting Requirements

EPA is proposing that all data developed under this rule be reported in accordance with its TSCA Good Laboratory Practice (GLP) standards that appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans at least 30 days prior to the initiation of each study.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. The Agency is proposing specific reporting requirements for each of the proposed test standards as follows:

1. The biodegradation tests shall be completed, and the final reports submitted to EPA within one year of the effective date of the final test rule. Quarterly progress reports shall be required.

2. The acute toxicity tests in aquatic vertebrates, aquatic invertebrates, and in algae shall be completed, and the final reports submitted to EPA within one year of the effective date of the final test rule. Quarterly progress reports shall be required.

3. The sediment toxicity test with *Rhepoxynius abronius* shall be completed, and the final report submitted to EPA within one year of the effective date of the final test rule. Quarterly progress reports shall be required.

4. The aquatic vertebrate and invertebrate chronic toxicity tests shall be completed, and the final reports submitted to EPA within two years of the effective date of the final test rule. Quarterly progress reports shall be required.

5. The bioconcentration tests in fish and oyster shall be completed, and the final reports submitted to EPA within one year of the effective date of the final test rule. Quarterly progress reports shall be required.

6. The reproduction test in Mallard ducks shall be completed, and the final reports submitted to EPA within eighteen months of the effective date of the final test rule. Quarterly progress reports shall be required.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the **Federal Register** as required by section 4(d).

Persons who export a chemical substance or mixture that is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR Part 707 (45 FR 82844; December 16, 1980). In brief, as of the effective date of the final test rule, an exporter of OMCTS must report to EPA the first annual export or intended export of OMCTS to any one country. EPA will notify the foreign country concerning the test rule for the chemical.

E. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records; (2) submit reports, notices, or other information; or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *." The Agency considers a testing facility to be a place where the chemical is held or stored, and therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with any final rule for OMCTS. These inspections may be conducted for purposes which include verification that testing has begun, that

schedules are being met, and that reports accurately reflect the underlying raw data and interpretations and evaluations to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of the TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and to include such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing after the deadlines for such submissions. Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

V. Issues for Comment

1. Because OMCTS is expected to partition strongly to sediment, the Agency believes that toxicity testing of benthic orgnisms *i.e.* vertebrates, invertebrates, or plants dwelling on bottom sediment or burrowing or rooting into the sediment itself, would be most appropriate in characterizing the environmental effects of aquatic releases of OMCTS. However except for sediment bioassays, such as the proposed test with *Rhepoxynius*, (which focuses on sediment toxicity rather than specific toxicity to benthic organisms) the Agency is not aware of any standard test methods for toxicity testing of benthic organisms exposed to sediment sorbed chemicals. The Agency solicits comments on the need for testing OMCTS toxicity to benthic organisms not only in the water column, but those dwelling in or on OMCTS—containing sediments and on the availability of appropriate test methods.

2. The Corps of Engineers and the USEPA Environmental Research Laboratory at Narragansett, RI, recently developed and validated a test method to determine acute and chronic toxicity to the epifaunal invertebrate *Mysidopsis* and to the infaunal invertebrate *Ampelisca*. The method is described in a draft technical report entitled "The Application of Population Responses for Evaluating the Effects of Dredged Material." The Agency requests comments on its appropriateness for testing OMCTS. A copy of the report is in the OPTS docket for this rulemaking.

3. For the marine sediment toxicity assay, the Agency believes that OMCTS-spiked sediment should be tested at levels representative of those reported in aquatic environmental studies discussed in Unit B. The Agency requests comments on the selection of numbers and levels of samples for testing.

4. EPA is not aware of a standard method to determine chronic toxicity to *Crassostrea virginica*, and the Agency welcomes information concerning the availability of such a method.

5. EPA requests comments on the suitability of the proposed biodegradation test methods in light of the volatile nature of OMCTS. Comments on protocol modification and/or the recommendation of other test methods designed for volatile materials would be welcome.

6. OMCTS is part of a family of silicone compounds (PDMS) including not only the tetramer OMCTS, but also the trimer and the pentamer. The trimer and pentamer are present as impurities at levels of 2 to 4 percent in commercial OMCTS. Also, the trimer and/or pentamer may be intentionally added by the manufacturer to adapt OMCTS for certain formulation characteristics. The Agency has proposed testing on pure OMCTS (99 percent purity), but it would welcome comments on whether the testing of formulations containing a significant amount of trimer and/or pentamer would be desirable and feasible.

7. The silicone polymers and manufactured from the three PDMS discussed in Unit V.6 above. Silicone polymers are of three classes: Fluids, elastomers, and resins. There are only minimal environmental and chemical fate data available on PDMS and silicone polymers. The Agency may propose additional testing in the future of other PDMS and the silicone polymers in order to characterize this group of chemicals. The Agency requests comment on this approach. Any further action would be proposed in a separate notice.

VI. Economic Analysis of Proposed Rule

To assess the economic impact of this rule, EPA has prepared an economic analysis that evaluates potential for significant economic impacts on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these costs by examining four market characteristics of OMCTS: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations.

Total testing costs for the proposed rule for OMCTS are estimated to range from $60,200 to $181,200. The annualized test cost (using a cost of capital of 25 percent over a period of 15 years) range from $15,592 to $46,931. Based on the production volume range reported for 1984 under section 8(a) of TSCA, 110 million pounds to 130 million pounds, the unit test costs range from 0.014 to 0.043 cents per pound. Relative to a current list price of $2.07 per pound (00 percent purity) for OMCTS, these costs are equivalent to 0.007 to 0.02 percent of price.

Based on these costs and the market characteristics of OMCTS, the economic analysis indicates that the potential for significant adverse economic impact as a result of this test rule is low. This conclusion is based on the following observations:

1. The annual unit cost of the testing required in this rule is very low;

2. Demand for OMCTS appears relatively inelastic due to its dominant use as a captive intermediate; and

3. The market expectations for OMCTS are optimistic.

Refer to the economic analysis which is contained in the public record for this rulemaking for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

VII. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, (703) 487-4650 (PB 82-140773). On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing in this proposed rule.

VIII. Availability of Test Guidelines

The following guidelines, study plans and other relevant sources of information cited in this rulemaking are available from the following sources: American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, (215-299-5400).

IX. Public Meetings

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting subsequent to the close of the public comment period in Washington, DC. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): Toll Free: (800-424-9065); In Washington, DC: (554-1404); Outside the U.S.A. (Operator-202-554-1404), by December 16, 1985. A meeting will not be held if members of the public do not indicate that they wish to make oral presentations. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to verify whether a meeting will be held.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

X. Public Record

EPA has established a record for this rulemaking, (docket number OPTS-42071). This record contains the basic information considered by the Agency in developing this proposal, and appropriate Federal Register notices.

This record includes the following information:

A. Supporting Documentation

(1) Federal Register notices pertaining to this rule consisting of:

(a) Notice containing the ITC designation of OMCTS to the Priority List (49 FR 46931; November 29, 1984).

(b) Rules requiring TSCA section 8(a) and 8(d) reporting on OMCTS (49 FR 46739 and 46741; November 28, 1984).

(c) TSCA test guidelines cited as test standards for this rule.

(1) OMCTS economic analysis.

(2) ASTM sediment toxicity bioassay method cited as a test standard for this rule.

(3) Communications before proposal consisting of:

(a) Written public comments and letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(5) Reports—published and unpublished factual materials.

B. References

(1) U.S. Environmental Protection Agency. Internal memorandum from Patricia Harrigan, Design and Development Branch, to Jeffrey Davidson, Test Rules Development Branch. Chemical Property and Environmental Behavior Estimates for Chemicals on the 15th ITC Priority List. November 29, 1984.

(2) U.S. Environmental Protection Agency. Computer printout: Graphic Exposure Modeling System (GEMS) EXAMS and ENPART models. Washington, D.C. Office of Toxic Substances, USEPA. 1985.

(3) Dow Corning Corporation. "Water Solubility of PDMS" Letter with attached studies from Cecil L. Frye to Martha G. Price. Environmental Protection Agency. December 12, 1984.

(4) Vogal, G.E., and F.O. Stark. "Mutual Solubilities in Water-Permethylsiloxane Systems." *J. Chem. Eng. Date* 9(4):555-601. October 1964.

(5) Bruggemen, W.A. *et al.* "Absorption and Retention of Polydimethylsiloxanes (Silicones) in Fish, Preliminary Experiments." *Toxicol. Environ. Chem.* 7(4):287-298. 1984.

(6) Dow Corning Corporation. Unpublished study of T.H. Lane and C.L. Frye. Letter with attached studies from Cecil L. Frye to Martha G. Price. Environmental Protection Agency. December 12, 1984.

(7) Kenaga, E.E. "Predicted Bioconcentration Factors and Soil Sorption Co-efficients of Pesticides and Other Chemicals." *Ecotoxicol. Environ. Safety.* 4:26-38. 1980.

(8) Interagency Testing Committee (ITC) Fifteenth Report to the Administrator and Request for comments. 49 FR 46931. November 29, 1984.

(9) Atkinson, R. "Predicting Gas Phase Organic Molecule Reaction Rates Using Linear Free Energy Correlations. I. O(^{3}P) and OH Addition and Abstraction Reactions." *J. Chem. Kinetics.* 12:761-765. 1980.

(10) Gay, B.W., Jr., and J.J. Bufalini. "Laboratory Reactivity Studies of Octamethylcyclotetrasiloxane." Environmental Sciences Research Laboratory, Research Triangle Park, NC. Submitted to EPA Region 2. March 1979.

(11) Dow Corning Corporation. "Photochemical Oxidation of Methylsilicon Moieties in the Gas Phase." Letter with attached studies from Cecil L. Frye to Martha G. Price. Environmental Protection Agency. December 12, 1984.

(12) Abe, Y. *et al* "Photolytic Oxidative Degradation of Octamethylcyclotetrasiloxane and Related Compounds." *J. Macromol. Sci.-Chem.* A16(2):461-471. 1981.

(13) U.S. Environmental Protection Agency. Computer printout: Production statistics for chemicals in the nonconfidential initial TSCA inventory. Retrieved January 1985. Washington, DC: Office of Pesticides and Toxic Substances. 1985.

(14) Dow Corning Corporation. Letter with attached studies from E.J. Hobbs to M. Grief, Chairman, Interagency Testing Committee. December 16, 1982.

(15) Browing, G.R. Silicone, Products Division, General Electric Co. Personal communication with M.G. Price, U.S. Environmental Protection Agency. February 20, 1985.

(16) General Electric Company. Polydimethylsiloxane fluids environmental impact analysis. 1977.

(17) Browning, G.R. Silicone Products Division, General Electric Co. Personal communication with M.G. Price, U.S. Environmental Protection Agency. May 23, 1985.

(18) General Electric Co. Silicone Products Data Sheet #CDS-4132. November 1980.

(19) Pellenbarg, R. "Environmental poly(organosiloxanes) (Silicones)." *Environ. Sci. & Technol.* 13(5):565-568. May 1979.

(20) Pellenbarg, R. "Silicones in Chesapeake Bay Sediments." *Marine Pollution Bulletin.* 13(12):427-429. 1982.

(21) Pellenbarg, R. "Silicones as Tracers for Anthropogenic Additions to Sediments." *Marine Pollution Bulletin.* 10:267-269. 1979.

(22) Watanabe, N. *et al.* "Distribution of Organosiloxanes (Silicones) in Water, Sediments and Fish from the Nagara River Watershed, Japan." *Sci. Total Environ.* 35:91-97. 1984.

(23) Watanabe, N. *et al.* "Determination of Trace Amounts of Siloxanes in Water, Sediments and Fish Tissues by Inductively Coupled Plasma Emission Spectrometry." *Sci. Total Environ.* 34:169-176. 1984.

(24) de Groot, R. "A method for a rapid semi-quantitative determination of gas-chromatographable organic matter in surface water." *H_2O.* 12 (15):333–336. 1979

(25) Bailey, Walter. Blue Plains Wastewater Treatment Plant. Summarized telephone conversation with J. Jackson, Syracuse Research Corporation, Syracuse, NY. March 12, 1985.

(26) A.F. Houghton, Valley Forge, PA. Summarized telephone conversation with J. Jackson, Syracuse Research Corporation, Syracuse, NY. March 12, 1985.

(27) Dow Corning Corporation. "Biochemical Oxygen Demand of Octamethylcyclotetrasiloxane." Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. December 28, 1984.

(28) Dow Corning Corporation. "Biological Oxygen Demand of Tetramethyldisiloxanediol." Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. December 12, 1984.

(29) Dow Corning Corporation. "Twenty Day Biochemical Oxygen Demand of Dimethylsilanediol with Bacterial Isolates Previously Exposed to Silicones." Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. December 12, 1984.

(30) Dow Corning Corporation. Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. December 12, 1984.

(31) Frye, Cecil L. Dow Corning Corporation. Presentation, USEPA Public Meeting, December 19, 1984.

(32) Bellama, J.M. Department of Chemistry, University of Maryland. Unpublished studies and personal communication with M.G. Price, U.S. Environmental Protection Agency. March 25, 1985.

(33) Dow Corning Corporation. "Four-day Static Aquatic Toxicity with TX-1283 in Freshwater and Saltwater Species." Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. December 28, 1984.

(34) Dow Corning Corporation. "Acute toxicity test with *Daphnia magna*-Octamethylcyclotetrasiloxane." Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. December 28, 1984.

(35) Dow Corning Corporation. "Primary Insecticidal and Miticidal Screening of Octamethylcyclo-tetrasiloxane." Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency, December 28, 1984.

(36) Dow Corning Corporation. "Algal assay-bottle Test: Octamethylcyclotetrasiloxane." Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. December 28, 1984.

(37) Dow Corning Corporation. "Bioconcentration of Octamethylcyclotetrasiloxane in Fish." Letter with attached studies from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. December 28, 1984.

(38) Dow Corning Corporation. Letter with attached tables of numerical data to supplement "Bioconcentration of Octamethylcyclotetrasiloxane in Fish" from Cecil L. Frye to Martha G. Price, Environmental Protection Agency. May 24, 1985.

(39) U.S. Environmental Protection Agency. Internal memorandum from S.J. Ellis, Environmental Effects Branch, to M.G. Price, Test Rules Development Branch. Review of OMCTS Bioconcentration Study. June 6, 1985.

(40) Bourquin, A.W., Hood, M.A., Garnas, R.I. An artificial microbial ecosystem for determining effects and fate of toxicants in a salt-marsh environment. *Development in Industrial Microbiology* 16:185–191. 1977.

EPA will supplement this record with additional relevant information as it is received. Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Rm. E–107, 401 M St., SW., Washington, D.C. from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

XI. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order, i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96–354, September 19, 1980) EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) They are not expected to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs, if any, in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB number 2070–0033. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB marked "Attention: Desk Officer for EPA." The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects

40 CFR Part 797

Testing, Environmental protection, Chemical fate, Environmental effects, Health effects, Chemicals.

40 CFR Part 799

Testing, Environmental protection, Hazardous material, Chemicals.

Dated: October 22, 1985.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 797—[AMENDED]

1. It is proposed that Part 797 be amended as follows:

a. The authority citation for Part 797 continues to read as follows:

Authority: 15 U.S.C. 2603.

b. In § 797.1400, paragraphs (d)(2)(vi)(B) and (d)(3) (ii) and (iii) are revised, to read as follows:

§ 797.1400 Fish acute toxicity test.

* * * * *

(d) * * *

(2) * * *

(vi) * * *

(B) The concentration of dissolved oxygen in the dilution water should be between 90 and 100 percent saturation; 9.8 to 10.9 mg/l for tests with trout, and 8.0 to 8.9 mg/l for tests with bluegill or fathead minnow at sea level. For silversides and sheepshead minnow assuming the salinity is 20 ppt and the tests are performed at sea level at 25 °C, then the dissolved oxygen content should be 6.6 to 7.4 mg/l. If necessary, the dilution water can be aerated before the addition of the test substance. All reconstituted water should be aerated before use. Buffered soft water should be aerated before but not after the addition of buffers.

(3) * * *

(ii) *Dissolved oxygen concentration.* (A) During static tests with rainbow trout the dissolved oxygen in each test chamber should be greater than 5.5 mg/l. In tests with bluegill and fathead minnows, the DO should be maintained above 4.5 mg/l. In tests with silversides and sheepshead minnows, the DO should be maintained above 3.7 mg/l.

(B) During flow-through tests the dissolved oxygen concentration should be maintained above 8.2 mg/l in tests with trout, above 6.6 mg/l in tests with

bluegills or fathead minnows, and above 5.5 mg/l in tests with silversides and sheepshead minnows.

(iii) *Temperature.* The test temperature should be 22±1 °C for bluegill and fathead minnows, 12±1 °C for rainbow trout, and 25±1 °C for silversides and sheepshead minnows. The temperature should be measured at least hourly in one test chamber.

PART 799—[AMENDED]

2. It is proposed that 40 CFR Part 799 be amended as follows:

a. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

b. In Part 799 by adding new § 799.3100, to read as follows:

§ 799.3100 Octamethylcyclotetrasiloxane.

(a) *Identification of test substance.* (1) Octamethylcyclotetrasiloxane (CAS No. 556-67-2) (hereinafter "OMCTS") shall be tested in accordance with this section.

(2) Octamethylcyclotetrasiloxane of at least 99.0 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (import) or process octamethylcyclotetrasiloxane other than as an impurity, after the effective date of this final rule December 13, 1985 to the end of the reimbursement period shall submit exemption applications, submit study plans, conduct tests (in accordance with Part 792 of this chapter), and submit data as specified in this section, Subpart A of this Part, and Part 790 of this chapter for single-phase rulemaking.

(c) *Performance criteria*—(1) In all testing required under this section, OMCTS levels shall be monitored (measured) immediately prior to the start of the testing period, at a minimum of six intervals during the testing period, and at the end of the test.

(2) In the aquatic toxicity testing required under paragraph ~~(e)~~ of this section, the level of OMCTS as measured shall be maintained at a level greater than or equal to the initial concentration measured at the beginning of the testing period.

(3) In the sediment toxicity testing required under paragraph (e)(6) of this section, clean sediments having low, medium, and high clay content shall be spiked with a minimum of three levels of OMCTS.

(d) *Chemical fate*—(1) *Biodegradation.*—(i) *Required testing.* Biodegradation testing in water shall be conducted with OMCTS in accordance with the method described in Bourquin et al., *Developments in Industrial Microbiology* 18: 185–191. 1977. The method is available from the Office of the **Federal Register** Information Center, 11th and L St., NW., Washington, D.C., and the OPTS Reading Room (docket no. OPTS–42071, Environmental Protection Agency, 401 M St., Washington, DC). This incorporation by reference was approved by the Director of the Federal Register on [date]. The method is incorporated as it exists on the effective date of this rule; a notice of any change will be published in the **Federal Register.**

(ii) *Reporting requirements.* (A) The biodegradation test in water shall be completed and the final report submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(2) *Inherent biodegradability in soil*—(i) *Required testing.* Inherent biodegradability in soil tests to assess aerobic and anaerobic biodegradability shall be conducted with OMCTS in accordance with § 796.3400 of this chapter.

(ii) *Reporting requirements.* (A) The inherent biodegradability in soil tests shall be completed and the final report submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(3) *Biodegradability in sludge systems*— (i) *Required testing.* Biodegradability tests in sludge systems shall be conducted with OMCTS in accordance with § 796.3341 of this chapter.

(ii) *Reporting requirements.* (A) The biodegradability tests in sludge systems shall be completed and the final results submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(e) *Environmental effects*—(1) *Fish acute toxicity.*—(i) *Required testing.* Fish acute toxicity tests shall be conducted with OMCTS using *Pimephales promelas* (fathead minnow), *Salmo gairdneri* (rainbow trout), *Lepomis macrochirus* (bluegill sunfish), *Cyprinodon variegatus* (sheepshead minnow), and *menidia peninsulae* (silversides) in accordance with § 797.1400 of this chapter.

(ii) *Reporting requirements.* (A) The fish acute toxicity tests shall be completed and the final report submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(2) *Daphnid acute toxicity*—(i) *Required testing.* The daphnid acute toxicity test shall be conducted with OMCTS using *Daphnia magna* or *D. pulex* in accordance with § 797.1300 of this chapter.

(ii) *Reporting requirements.* (A) a daphnid acute toxicity test shall be completed and the final report submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(3) *Mysid acute toxicity*—(i) *Required testing.* A mysid acute toxicity test shall be conducted with OMCTS using *Mysidopsis bahia* in accordance with § 797.1930 of this chapter.

(ii) *Reporting requirements.* (A) The mysid acute toxicity test shall be completed and the final report submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(4) *Oyster acute toxicity*—(i) *Required testing.* An oyster acute toxicity test shall be conducted with OMCTS using *Crassostrea virginica* in accordance with § 797.1800 of this chapter.

(ii) *Reporting requirements.* (A) The oyster acute toxicity test shall be completed and the final report submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(5) *Algal acute toxicity*—(i) *Required testing.* (A) Algal acute toxicity tests shall be conducted with OMCTS using *Selenastrum capricornutum* and *Skeletonema costatum* in accordance with § 797.1050 of this chapter and modifications specified in paragraph (e)(5)(i)(B) of this section.

(B) Modification. The requirement under § 797.1050 (c)(6)(i)(B) of this chapter is modified to require that the final separation of the algal cells from the test solution be done using an ultrafiltration (e.g. 0.45 micrometer pore size) technique.

(ii) *Reporting requirements.* (A) The algal acute toxicity tests shall be completed and the final report submitted

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to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(6) *Sediment toxicity*—(i) *Required testing.* A sediment toxicity test shall be conducted using OMCTS-spiked clean sediments having low medium, and high clay content according to the method of R.C. Swartz et al., "Phoxocephalid Amphipod Bioassay for Marine Sediment Toxicity," as published in the American Society for Testing and Materials Special Technical Publication 854, R.C. Cardwell et al. (eds.), American Society for Testing and Materials, Philadelphia, 1985, pp. 284–307 which is incorporated by reference. This document is available for inspection at both the Office of the Federal Register Information Center and the OPTS Reading Room (docket no. OPTS 42071). This incorporation by reference was approved by the Director of the Federal Register on (DATE). This material is incorporated as it exists on the date of approval, and a notice of any change will be published in the Federal Register.

(ii) *Reporting requirements.* (A) The sediment toxicity test shall be completed and the final report submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(7) *Fish chronic toxicity*—(i) *Required testing.* A fish chronic toxicity test shall be conducted with OMCTS using the most sensitive fish (with the lowest LC_{50}) from the acute toxicity testing conducted in accordance with paragraph (e)(i) of this section. The fish chronic toxicity test shall be conducted in accordance with § 797.1600 of this chapter.

(ii) *Reporting requirements.* (A) The fish chronic toxicity test shall be completed and the final report submitted to the Agency within two years of the effective date of the final rule.

(B) The protocol for the chronic study must be submitted within 30 days of the submission of the final report on the fish acute toxicity studies. Quarterly progress reports shall be submitted to the Agency beginning 90 days after submission of the study plan for this test.

(8) *Daphnid chronic toxicity*—(i) *Required testing.* A Daphnid chronic toxicity test shall be conducted with OMCTS using *Daphnia magna* or *D. pulex* in accordance with § 797.1330 of this chapter.

(ii) *Reporting requirements.* (A) The Daphnid chronic toxicity test shall be completed and the final report submitted to the Agency within two years of the effective date of the final rule.

(B) The protocol for the chronic study must be submitted within 30 days of the submission of the final report on the daphnid acute toxicity study. Quarterly progress reports shall be submitted to the Agency beginning 90 days after submission of the study plan for this test.

(9) *Mysid chronic toxicity*—(i) *Required testing.* A Mysid chronic toxicity test shall be conducted with OMCTS using *Mysidopsis bahia* (mysid shrimp) in accordance with § 797.1950 of this chapter.

(ii) *Reporting requirements.* (A) The mysid chronic toxicity test shall be completed and the final report submitted to the Agency within two years of the effective date of the final rule.

(B) The protocol for the chronic study must be submitted within 30 days of the submission of the final report on the mysid acute toxicity study. Quarterly progress reports shall be submitted to the Agency beginning 90 days after submission of the study plan for this test.

(10) *Bioconcentration in fish*—(i) *Required testing.* A bioconcentration test shall be conducted with OMCTS using *Pimephales promelas* (fathead minnow) in accordance with § 797.1520 of this chapter.

(ii) *Reporting requirements.* (A) The bioconcentration test shall be completed and the final report submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(11) *Bioconcentration in oyster*—(i) *Required testing.* A bioconcentration test shall be conducted with OMCTS using *Crassostrea virginica* (oyster) in accordance with § 797.1830 of this chapter.

(ii) *Reporting requirements.* (A) The bioconcentration test shall be completed and the final report submitted to the Agency within one year of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(12) *Mallard reproduction*—(i) *Required testing.* A Mallard reproduction test shall be conducted with OMCTS in accordance with § 797.2150 of this chapter.

(ii) *Reporting requirements.* (A) The reproduction test shall be completed and the final report submitted to the Agency within eighteen months of the effective date of the final rule.

(B) Quarterly progress reports shall be submitted to the Agency beginning 90 days after the effective date of the final test rule.

(Information collection requirements have been approved by the Office of Management and Budget under control number 2070–0033.)

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